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TOPE-MCKAY & ASSOCIATES
23852 PACIFIC COAST HIGHWAY #311
MALIBU, CA 90265

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,162	BUEHLER, MARTIN	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) *35-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al. US 4,871, 440 ("Nagata").

Nagata discloses an electro-active sensor for detecting electro-active species in solution, comprising:

a nonconductive platform ((1) the electrode body 1 is clearly nonconductive because it were not the sensor would not work as the electrodes would be shorted out), the nonconductive platform having a first side and a second side (Figure 1);

a first electrode set attached with a first side of a nonconductive platform (Figure 1), wherein the first electrode set further comprises:

a first conductive via passing through the nonconductive platform

from the first side to the second side (shown, but not labeled, in Figure 1);

a first electrode (2) attached with the first conductive via on the first side, where the first electrode serves as a first working electrode (col. 04:59);

a second conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 1);

a second electrode (3') attached with the second conductive via on the first side (Figure 1), where the second electrode serves as a first reference electrode (col. 04:59-60);

a third conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 1); and

a third electrode (3) attached with the third conductive via on the first side, where the third electrode serves as an first auxiliary electrode (col. 04:60), whereby the working electrode, the reference electrode, and the auxiliary electrode serve as a electrochemical cell that may be utilized to detect the electro-active species in the solution (the abstract).

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Matson US 4,404, 065 ("Matson").

Matson discloses an electro-active sensor for detecting electro-active species in solution, comprising:

a nonconductive platform, the nonconductive platform having a first side and a second side (Figure 1);

a first electrode set attached with a first side of a nonconductive platform (Figure 17), wherein the first electrode set further comprises:

a first conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 17);

a first electrode (150) attached with the first conductive via on the first side (Figure 17) , where the first electrode serves as a first working electrode (col. 08:21-29);

a second conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 17);

a second electrode (160) attached with the second conductive via on the first side (Figure 17), where the second electrode serves as a first reference

electrode (col. 08:45);

a third conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 17); and

a third electrode (158) attached with the third conductive via on the first side, where the third electrode serves as an first auxiliary electrode (col. 08:44), whereby the working electrode, the reference electrode, and the auxiliary electrode serve as a electrochemical cell that may be utilized to detect the electro-active species in the solution (the abstract).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 3, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata et al. US 4,871, 440 ("Nagata") in view of Weetall US 5,066,372 ("Weetall").

Addressing claim 2, Nagata discloses an electro-active sensor for detecting electro-active species in solution, comprising:

a nonconductive platform ((1) the electrode body 1 is clearly nonconductive because it were not the sensor would not work as the electrodes would be shorted out), the nonconductive platform having a first side and a second side (Figure 1);

a first electrode set attached with a first side of a nonconductive platform (Figure 1), wherein the first electrode set further comprises:

a first conductive via passing through the nonconductive platform

from the first side to the second side (shown, but not labeled, in Figure 1);

a first electrode (2) attached with the first conductive via on the first

side, where the first electrode serves as a first working electrode (col. 04:59);

a second conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 1);

a second electrode (3') attached with the second conductive via on the first side (Figure 1), where the second electrode serves as a first reference electrode (col. 04:59-60);

a third conductive via passing through the nonconductive platform from the first side to the second side (shown, but not labeled, in Figure 1); and

a third electrode (3) attached with the third conductive via on the first side, where the third electrode serves as an first auxiliary electrode (col. 04:60), whereby the working electrode, the reference electrode, and the auxiliary electrode serve as a electrochemical cell that may be utilized to detect the electro-active species in the solution (the abstract).

Nagata does not mention providing a plurality of electrode sets. However, this is just mere multiplication of parts for multiplied effects. MPEP 2144.04.VI.B. Moreover, as shown by Weetall it was known at the time of the invention to provide a plurality of electrode sets on a substrate in a sensor. See Figure 1. This will allow several samples so to be analyzed simultaneously.

Addressing claims 3 and 21, for the additional limitations of these claims see Figures 1 and 3 and note especially elements 61, 62, and 63.

7. Claims 4-9, 22, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata in view of Weetall as applied to claims 2, 3, and 21 above, and further in view of Liu US 4,655,880 ("Liu") and Watanabe US 4,647,362 ("Watanabe").

Addressing claims 4 and 23, Nagata as modified by Weetall does not mention possible materials from which to make the nonconductive platform. Liu and Watanabe, however, show that glass and ceramics, along with other materials, such as various plastics, were considered conventional materials from which to make electrode supports for electrodes in an electro-active sensor. See in Liu col. 10:43-048 and in Weetall col. 03:55-59. So barring contrary evidence, the choice of material to make the platform from known materials for such purpose was within the skill of one with ordinary skill in the art at the time of the invention. Some factors that would be considered are desired mechanical strength, transparency, and thermal, chemical, and electrical resistance.

Addressing claims 5 and 24, for the additional limitation of this claim consider Figure 1 in Nagata and Figure 1 in Weetall. As shown by these Figures in the Nagata as modified by Weetall and Liu and Watanabe the electrodes would be formed in a substantially co-planar manner.

Addressing claims 6 and 22, since "a plane of the nonconductive platform" is arbitrary, this limitation is met by Nagata.

Addressing claims 7-9, 25, 26, 27, for the additional limitation of this claim consider Figures 2, 9, and 10 in Nagata. For claim 9 note that although in the embodiment shown in Figure 2 of Nagata the reference electrode surrounds the auxiliary electrode to have the reference electrode surround the auxiliary electrode is just reversal or rearrangement of parts, which is per se obvious. MPEP 2144.04.VI.

8. Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata in view of Weetall, Liu, and Watanabe as applied to claims 4-9, 22-27 above, and further in view of Maley et al., US 5,494,562 ("Maley")

Nagata as modified by Wetall, Liu, and Watanbe does not disclose having the first auxiliary electrode from the first electrode set be connected to the second auxiliary electrode from a second electrode set. Maley discloses having a first working electrode and a second working electrode share a counter electrode. See Figure 9A and col. 06:14-26 and col. 16:01-13. It would have been obvious to one with ordinary skill in the art at the time of the invention to have one of the first working electrode of the first electrode set or the second working electrode of the second electrode set be an actual working electrode and the other working electrode be an interference correcting electrode as taught by Maley because then the measurement made at the actual working electrode will be more accurate as these measurements can be corrected for background discerned by the interference correcting electrode. See col. 06:14-26 and col. 16:01-13. However ,as seen from Figure 1 of Naragata and Figure 1 of Weetall the electrode sets are separated so If one of the first working electrode of the first electrode set or the second working electrode of the second electrode set is to be made an interference correcting electrode then the two counter electrodes should be connected together to help ensure that measurement regime for each electrode set is otherwise the same.

9. Claims 11, 12, 20, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata in view of Weetall, Liu, Watanabe, and Maley as applied to claim 10 above, and further in view of Mansouri et al. US 6,652,720 B1 ("Mansouri")

Addressing claim 11, Nagata as modified by Weetall, Liu, Watanabe, and Maley does not mention having the first and second auxiliary electrodes be connected with a common ground.

Mansouri discloses an electrode set comprising a plurality of working electrodes, a reference electrode, and a counter electrode. See the abstract; and Figure 2. Mansouri also discloses having the counter electrode (which has been construed in Nagata as an auxiliary electrode) be grounded. See col. 15:65 - col. 16:03. Barring a contrary showing, in light of Mansouri, the choice of potentials to apply the electrodes is just a matter of optimizing the operating parameters for the analyte of interest. This is especially so since no analyte is claimed.

Addressing claims 12 and 28, for the additional limitation of this claim see in Nagata col. 05:08-12.

10. Claims 13-17 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata in view of Weetall, Liu, Watanabe, Maley, and Mansouri as applied to claims 11, 12, 20, 28 above, and further in view of Leader et al. US 5,336,388 (“Leader”), Zelin US 5,821,399 (“Zelin”), the Derwent abstract of Furusawa et

al. JP 10-48177 A ("Furusawa"), and the JPO abstract of Miyashita et al. JP 2000-19146 A ("Miyashita").

Nagata as modified by Weetall, Liu, Watanabe, Maley, and Mansouri does not mention providing a pH sensor, conductivity sensor, and heater as claimed.

Leader discloses an analyte and pH measurement sensor assembly and method. The sensor assembly includes a pH sensor, a heater, and thermistor "… to indicate the temperature at any time on the substrate …". See col. 07:09-10; col. 11:38-43; col. 11:62-67; and col. 10:26-40. Zelin discloses a real-time fluid analysis sensing device provided with a pair of electrodes comprising a conductivity sensor. See col. 03:42-55. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a pH sensor and heater as taught by Leader and a conductivity sensor as taught by Zelin in the invention of Nagata as modified by Weetall, Liu, Watanabe, Maley, and Mansouri because in Nagata the analyte measurement based on an enzyme reaction (col. 05:18-25) and it was well known in the art at the time of the invention that enzyme activity is affected by solution pH and temperature. So, by providing a pH sensor the measurement can be corrected for slight pH shifts from the pH at which optimum enzyme activity occurs and with that heater the measurement zone can be heated so that the enzyme is at the temperature at which the reagent enzyme has optimum activity. See, for example, Furusawa and Miyashita. As for the conductivity sensor, as taught by Zelin it "… allows the instrument to monitor the test and, by comparing measurement data to factory preset thresholds, determine whether test p[parameters are deviating form the standard limits." See col. 03:43-55. As for

using a four-terminal conductivity sensor and a two-terminal heater, the heater (86) in Leader has four terminals and the conductivity sensor in Zelin apparently has two terminals (col. 03:45-49). However, barring a contrary showing the number of terminals on the heater and the conductivity sensor is not critical. Fewer or more terminals may provided depending on whether the sensor is configured so that it can be attached to a meter at multiple sites on the sensor, on the size of heater and conductivity sensor, and on whether the heater or conductivity sensor has multiple[le segments for heating or making measurements in different parts of the sensor.

11. Claims 18 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata in view of Weetall, Liu, Watanabe, Maley, Mansouri, Leader, Zelin, Furusawa, and Miyashita as applied to claim 17 (which includes the limitations of claim 1) above, and further in view of Moussy et al. US 6,366,794 B1 ("Moussy").

Nagata in view of Weetall, Liu, Watanabe, Maley, Mansouri, Leader, Zelin, and Furusawa does not mention the circuitry claimed, although Nagata does disclose at least the claimed potentiostat circuit. See col. 05:42-66.

Moussy discloses an implantable potentiostat telemetry unit for electrochemical sensors comprising circuitry as set forth in claim 18. See the abstract; Figures 1-5; col. 01:64 – col. 05:13; and claim 1. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide circuitry as taught by Moussy in the invention of Nagata in view of Weetall, Liu, Watanabe, Maley, Mansouri, Leader, Zelin,

and Furusawa because this will allow the sensor of Nagata to accurately transmit data by telemetry with reduced power consumption compared to previous telemetried systems. The sensor of Nagata in view of Weetall, Liu, Watanabe, Maley, Mansouri, Leader, Zelin, and Furusawa then with adequate scaling down in size could be use in vivo for assisting the diagnose of ailments of patients. See in Moussy col. 01:01-60.

12. Claims 2, 3, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson US 4,404, 065 ("Matson").

Addressing claim 2, Matson discloses an electro-active sensor for detecting electro-active species in solution, comprising:

a nonconductive platform (150), the nonconductive platform having a first side and a second side (Figure 1);

a first electrode set attached with a first side of a nonconductive platform (Figure 17), wherein the first electrode set further comprises:

a first conductive via (164) passing through the nonconductive platform

from the first side to the second side (Figure 17);

a first electrode (154) attached with the first conductive via on the first side (Figure 17) , where the first electrode serves as a first working electrode (col. 08:21-29);

a second conductive via (164) passing through the nonconductive platform from the first side to the second side (Figure 17);

a second electrode (160) attached with the second conductive via on the first side (Figure 17), where the second electrode serves as a first reference electrode (col. 08:45);

a third conductive (172) via passing through the nonconductive platform from the first side to the second side (Figure 17); and

a third electrode (158) attached with the third conductive via on the first side, where the third electrode serves as an first auxiliary electrode (col. 08:44), whereby the working electrode, the reference electrode, and the auxiliary electrode serve as a electrochemical cell that may be utilized to detect the electro-active species in the solution (the abstract).

Although Matson does not specifically mention providing a plurality of electrode sets, this is strongly suggested by Figure 17, which shows two working electrodes (154, 156) and two reference electrode (160, 162). The counter electrode appears to be shared between the two pairs of working and reference electrodes. To provide separate counter electrodes would have been obvious to one with ordinary skill in the invention if this would increase the measurement accuracy of each electrode set.

Addressing claims 3 and 21, for the additional limitations of this claim note the leads shown at the top of Figure 17 and see col. 09:06-26, which clearly would also apply to embodiments with a plurality of electrode sets as suggested by Figure 17.

13. Claims 4-6 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson as applied to claims 2, 3, and 21 above, and further in view of Liu US 4,655,880 ("Liu") and Watanabe US 4,647,362 ("Watanabe").

Addressing claims 4 and 23, Matson only mentions several plastics from which to make the nonconductive platform. Liu and Watanabe, however, show that glass and ceramics, along with other materials, such as various plastics, were considered conventional materials from which to make electrode supports for electrodes in an electro-active sensor. See in Liu col. 10:43-048 and in Weetall col. 03:55-59. So

barring contrary evidence, the choice of material to make the platform from known materials for such purpose was within the skill of one with ordinary skill in the art at the time of the invention. Some factors that would be considered are desired mechanical strength, transparency, and thermal, chemical, and electrical resistance.

Addressing claims 5 and 24, for the additional limitation of this claim see Figure 17 in Matson.

Addressing claims 6 and 22, since "a plane of the nonconductive platform" is arbitrary, this limitation is met by Matson.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) claim 1: is the "a nonconductive platform" in line 5 the same as the "the nonconductive platform" in line 3?

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/

Primary Examiner, Art Unit 1795

September 30, 2008